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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

| EXAMINER | |
|---|---|
| MCEVOY, THOMAS M | |

| ART UNIT | PAPER NUMBER |
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| 3731 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/763,825 | WEBER ET AL. | |
| | Examiner | Art Unit | |
| | THOMAS MCEVOY | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *7/21/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28,30-38,43,50-63,65,66,69-76 and 78-87* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-13,15,16,24,25,28,30-32,34-38,50,52,54,56,57,60,61,63,71-74 and 80-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,43,51,53,55,58,59,62,65,66,69,70,75,76,78 and 79.

## DETAILED ACTION

1. Currently claims 1-28, 30-38, 43, 50-63, 65, 66, 69-76 and 78-87 are pending. Claims 7, 8, 14, 17-23, 26, 27, 33, 43, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, 75, 76, 78 and 79 have been withdrawn. Claims 29, 39-42, 44-49, 64, 67, 68 and 77 have been cancelled. Claims 1-6, 9-13, 15, 16, 24, 25, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 60, 61, 63, 71-74 and 80-87 are considered below.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 9-13, 15, 16, 24, 25, 28, 30-32, 34-38, 71-74 and 80-86 are rejected under 35 U.S.C. 102(e) as being anticipated by Couvillon (US 2003/0236531).

Regarding claims 1-3, 4, 12, 13, 71, 72, Couvillon discloses an elongate, elastic (paragraph 0048) catheter comprising (a) an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis (Figure 2A); and (b) an active region (area of members 110, Figures 2A-4) comprising a conductive polymer disposed over the elongate body such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the conductive polymer within the active region (paragraph 0040; polymer

is actuated by mass transfer of ions as are Applicant's polymers). Regarding claim 6, the active region can be a longitudinal strip (Figure 4). Regarding claims 81-83, the conductive polymer, electrolyte and counter electrode can be sealed in a structure (paragraph 0043).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 5, 9-11, 15, 16, 24, 25, 28, 30-38, 73, 74, 80, and 84-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) in view of Couvillon (US 2003/0236531).

Regarding claim 1, Maseda discloses a medical device comprising (a) an elongate body 114 adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; (b) a balloon 118; and (c) an active region (magnified secion, Figure 5) comprising a conductive polymer 500 disposed over the elongate body. Maseda fails to specifically disclose other types of electroactive polymers, such as those which are actuated by volumetric expansion, but clearly indicates that the electroactive polymer used in his disclosure is for explanatory purposes only. Couvillon discloses the device as described above where the electroactive polymer strands expand the end of the device in much the same way as a balloon (Figures 2, 7 and 8) which can overcome the stress exerted by smooth muscle

cells (paragraph 0039). It would have been obvious to one of ordinary skill in the art in that other regions of the Maseda device, such as the magnified portion in Figure 5, could be expanded by the Couvillon actuator strips because they can produce almost an identical structure (Figures 8A-B of Couvillon).

Regarding claim 5, Maseda discloses that said active region surrounds said elongate body in the form of a circumferential band (308, fig. 3B; col. 6, lines 4-7). Alternatively, since Couvillon discloses that the electroactive polymer strips can expand a balloon-like structure in a continuous band (except for being interrupted by aperture 103 (Figures 2A-B), it would have been obvious to one of ordinary skill in the art to expand the balloon of Maseda using strips in this circumferential configuration (though not interrupted by an aperture).

Regarding claims 9-11, as explained above, it would have been obvious to one of ordinary skill in the art to have incorporated the electroactive polymer actuator strips beneath, within or within recesses of the balloon of Maseda, and oriented them longitudinally as disclosed by Maseda, or circumferentially as disclosed by Couvillon. Maseda does not directly disclose that the recess of tube 114 (an incorporated into to be a circumferential recess or a longitudinal recess. Furthermore, regarding claims 9-11, Maseda does disclose a recess as described above (col.5, line 61) which could be used in/on tube 116 to actuate the balloon as explained above. Maseda also clearly discloses that various geometric configurations of the electroactive polymer actuator strips which would fit into the recesses are possible (col.8, lines 12-15). Maseda states that placement of the composite strands on the device has limitless configurations

(col.8, lines 15-16). Hence, if the recesses could be made into various configurations, than the recesses to hold them must also be the same shape. Therefore, it would have been obvious to a person of ordinary skill in the art that the recess formed in the elongated tubular body of the medical device could be of any shape, including circumferential or longitudinal.

Regarding claims 24, 25, 73, 74 and 80, Maseda discloses that one or more active regions are disposed such that at least a portion of the length of said medical device is stiffened upon expansion of the one or more active regions (col .2, lines 59-62; col. 5 line 64 to col. 6 line 3; col. 6 lines 13-17). Maseda discloses one or more of said active regions circumferentially surround the elongate body (col. 6, lines 38-41; col. 7 lines 1-4). Regarding claim 73 and 74, Maseda does not expressly disclose that the medical device is stiffened upon radial expansion or longitudinal expansion of said one or more of said active regions. However, Maseda discloses that various dynamic movements can be performed with the electroactive actuators (col. 3, lines 55-60; col. 8, lines 22-33). Hence, it is obvious that longitudinal and radial expansion, which are basic movements, are achieved by the actuators taught by Maseda.

Regarding claims 15, 16, 28, 34, 35, 37, 38, 80, 84 and 85, Maseda fails to disclose that the active region is incorporated into the balloon 118. However, Maseda further discloses: the electroactive polymer strands (i.e., 500) may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3-6); the circumferential band of composite strands expands and functions like a balloon (col. 6, lines 47-59); and the

balloon itself may incorporate the composite strands (col. 8, lines 6-9). Couvillon discloses the device as described above where the electroactive polymer strands expand the end of the device in much the same way as a balloon (Figures 2, 7 and 8) which can overcome the stress exerted by smooth muscle cells (paragraph 0039). It would have been obvious to one of ordinary skill in the art that the strands of Maseda can be used to expand the balloon 118 (which would serve as a passive deformable member) and incorporate the strands either within recesses of elastic balloon, within the balloon, or directly beneath the balloon as either orientation would be an obvious design choice and provide similar or identical results. Furthermore, since Maseda discloses that the strands can be contained within recesses of the outer tube 114 (col. 5, line 61), it would also be obvious to one of ordinary skill in the art to have attached the strands within recesses of tube 116 in order to expand the balloon; using the same structure shown in Figure 5 for example. It would have been obvious to one of ordinary skill in the art to have used the electroactive polymer actuator strips of Couvillon to expand the balloon since they are actually depicted as expanding a balloon-like structure and would perform very similar to the strands of Maseda.

Regarding claims 30-33, in the modified balloon of Maseda as described above, the active region would be able to radially expand the entire balloon, both proximal and distal portions.

Regarding claim 36, see above comments in regard to claims 9-11.

Regarding claim 86, in the modified balloon of Maseda in view of Couvillon as described above, the active region would be sealed by the balloon if the active region is installed within, beneath or within a recess of the balloon.

6. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) and Couvillon (US 2003/0236531) in view of Sharrow (US 4,793,359).

Regarding claim 87, Maseda as modified by Couvillon discloses the invention as described above comprising a plurality of active regions, where an active region can be one of the electroactive polymer actuator strips and where it would have been obvious to incorporate the strips within, underneath or within a recess of the balloon. Maseda fails to disclose that a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band. Sharrow teaches that a balloon in a balloon catheter can have two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon (col. 4, lines 4-5). It would have been obvious to one of ordinary skill in the art to have incorporated two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon.

7. Claims 50, 54, 56, 57, 60, 61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237).

Regarding claims 50, 54, 56, 57, 60 and 63, a balloon catheter comprising: (a) an insertable body 114 adapted for insertion into a body lumen of a patient; (b) a device

lumen within the insertable body (between tubes 114 and 116, Figure 2); (c) an inflatable balloon 118, wherein the interior of the balloon is in fluid communication with the device lumen, and (d) one or more electrically actuated members disposed along at least a portion of the length of the device lumen (magnified area of Figure 5 is disposed over the lumen), the one or more electrically actuated members being adapted to transform at least a portion of the length of the device between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into said body lumen of said patient (Figure 5 vs. Figure 5A). Maseda fails to disclose that the electroactive polymer strips (or active region) are used to expand the balloon. However, Maseda discloses: the electroactive polymer strands (i.e., 500) may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3- 6); the circumferential band of composite strands expands and functions like a balloon (col. 6, lines 47-59); and the balloon itself may incorporate the composite strands (col. 8, lines 6-9). It would have been obvious to one of ordinary skill in the art that the strands of Maseda can be used to expand the balloon 118 and incorporate the strands either within recesses of the elastic balloon, within the balloon, or directly beneath the balloon as either orientation would be an obvious design choice and provide similar or identical results. Furthermore, since Maseda discloses that the strands can be contained within recesses of the outer tube 114 (col. 5, line 61), it would also have been obvious to one of ordinary skill in the art to have attached the strands within recesses of tube 116 in

order to expand the balloon; using the same structure shown in Figure 5 for example. Regarding claim 63, the insertable body 114 can be extruded (col. 5, line 61).

### *Response to Arguments*

8. Applicant's arguments filed July 21st 2008 with respect to the 35 U.S.C 102(e) rejection of claim 50 have been fully considered and are persuasive. However, the 35 U.S.C. 103(a) rejection of claim 50 and dependents still applies and has been explained further above. The rejection, as presented here and previously, modifies the balloon of Maseda with the electroactive polymer strips (as shown in the magnified section of Figure 5, for example) in order to expand the balloon. This would result in the active region expanding a portion of the device that is in fluid communication with the device lumen. Examiner believes that Maseda has disclosed ample motivation for one of ordinary skill in the art to make such a modification and has cited the relevant passages above.

### *Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731